IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MATTHEW CONLEY and CANDI CONLEY,	:	
Plaintiffs	:	**No. 1:20-cv-00286**
v.	:	**(Judge Kane)**
ST. JUDE MEDICAL, LLC,	:	
Defendant	:	

MEMORANDUM

Before the Court is Defendant St. Jude Medical, LLC ("Defendant")'s motion to dismiss (Doc. No. 15) Plaintiff Matthew Conley and Plaintiff Candi Conley ("Plaintiffs")' amended complaint (Doc. No. 11-1) for failure to state a claim for which relief may be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the Court will grant Defendant's motion.

I. BACKGROUND

A. Procedural Background

Plaintiff initiated the above-captioned action on January 23, 2020 by filing a complaint in the Court of Common Pleas of York County. Former Defendant Abbott Laboratories removed the action to this court on February 18, 2020 pursuant to 28 U.S.C. § 1332. (Doc. No. 1.) The complaint asserted state claims against Defendant Abbott Laboratories for negligence, breach of warranty, strict liability, and loss of consortium. (Id. at 17-25.) Defendant Abbott Laboratories subsequently filed a motion to dismiss the complaint (Doc. No. 8) and a request for judicial notice (Doc. No. 9); however, before the motion to dismiss was fully briefed, Plaintiffs filed a motion for leave to amend their complaint to substitute St. Jude Medical, LLC as the appropriate defendant in this matter (Doc. No. 11). The Court granted Plaintiffs' motion on March 31, 2020.

(Doc. No. 12.) Plaintiffs' amended complaint alleges claims for negligence (Count I), breach of warranty (Count II), failure to warn/failure to report (Count III), liability for a defective product (Count IV), which the Court views as a claim for a manufacturing defect, and loss of consortium (Count V). (Doc. No. 11-1.) Defendant filed the instant motion to dismiss Plaintiff's amended complaint on April 28, 2020 (Doc. No. 15), accompanied by a renewed request for judicial notice (Doc. No. 16). Having been fully briefed (Doc. Nos. 17, 21, 23), the motion is ripe for disposition.

B. Factual Background [1]

Plaintiff Matthew Conley is an adult male and cancer patient who underwent a below-the-knee amputation as treatment. (Doc. No. 11-1 ¶¶ 1, 3.) On February 12, 2018, Plaintiff Matthew Conley had a Proclaim Dorsal Root Ganglion ("DRG") stimulator placed in order to treat chronic nerve pain related to his amputation. (Id. ¶ 4.) The Food and Drug Administration ("FDA") issued a Premarket Approval Letter for this device on November 22, 2016. (Id. ¶ 5.) Plaintiffs allege that the Proclaim DRG stimulator "was manufactured, sold, and placed in the stream of commerce by St. Jude Medical, LLC," and that it was "regularly tested by Brent Craver, an employee and/or representative of the Defendant." (Id. ¶¶ 6-7.)

Plaintiffs allege that Plaintiff Matthew Conley undergoes "regular MRI scans to check for the presence of cancer." (Id. ¶ 9.) The Proclaim DRG stimulator allegedly contains a switch to place it in "MRI mode" in order for a patient to have an MRI scan. (Id. ¶ 10.) Plaintiffs allege that on January 7, 2019, Plaintiff Matthew Conley was scheduled to undergo an MRI, "but could not due to the stimulator malfunctioning and not going into 'MRI mode.'" (Id. ¶ 11.) Plaintiffs

[1] The following factual background is taken from the allegations of Plaintiffs' amended complaint (Doc. No. 11-1).

allege that when Plaintiff Matthew Conley contacted Brent Craver about the malfunction, Mr. Craver informed him that the stimulator "was not reading properly" when it was last tested "on December 19, 2018." (Id. ¶ 13.) Plaintiff Matthew Conley underwent explant surgery to have the device removed on February 18, 2019. (Id. ¶ 16.) Plaintiffs allege that subsequent to this surgery, "an employee and/or representative of the Defendant . . . informed [] Plaintiff [Matthew Conley] that the Proclaim DRG stimulator had a warranty." (Id. ¶ 19.) Plaintiffs argue that as a result of the alleged device malfunction and subsequent surgery, Plaintiff Matthew Conley "suffered serious injuries" and "was forced to incur medical bills and expenses." (Id. ¶¶ 20-21.)

II. LEGAL STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing the sufficiency of a complaint pursuant to a motion to dismiss under Rule 12(b)(6), the Court must accept as true all material allegations in the complaint and all reasonable inferences that can be drawn from them, viewed in the light most favorable to the plaintiff. See In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 314 (3d Cir. 2010). However, the Court need not accept legal conclusions set forth as factual allegations. See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). Rather, a civil complaint must "set out 'sufficient factual matter' to show that the claim is facially plausible." See Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

Consistent with the Supreme Court's ruling in Twombly and Ibqal, the Third Circuit has identified three steps a district court must take when determining the sufficiency of a complaint under Rule 12(b)(6): (1) identify the elements a plaintiff must plead to state a claim; (2) identify any conclusory allegations contained in the complaint "not entitled" to the assumption of truth;

and (3) determine whether any "well-pleaded factual allegations" contained in the complaint "plausibly give rise to an entitlement to relief." See Santiago v. Warminster Twp., 629 F. 3d 121, 130 (3d Cir. 2010) (citation and quotation marks omitted). A complaint is properly dismissed where the factual content in the complaint does not allow a court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." See Iqbal, 556 U.S. at 678. Additionally, a court may not assume that a plaintiff can prove facts that the plaintiff has not alleged. See Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983).

III. DISCUSSION

Although Defendant does argue that Plaintiffs have inadequately pleaded the claims in their amended complaint, the instant motion is based primarily on Defendant's assertion that Plaintiffs' claims are preempted by federal law and, therefore, are barred. (Doc. No. 17 at 1-2, 6-12.) Accordingly, the Court will address the preemption issue at the outset.

A. Applicability of Preemption (Counts I, II, III, IV)

1. Legal Standard

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., sets out standards for FDA approval of pharmaceuticals. The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq., brought medical devices into the FDA's broad scheme of federal regulatory oversight and "established various levels of oversight for medical devices, depending on the risks they present." See Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Under this regulatory scheme, devices that are "represented to be for a use in supporting or sustaining human life" or "present a potential unreasonable risk of illness or injury" are designated as "Class III" devices and must generally receive premarket approval from the FDA.

See id. at 317. Further, "[o]nce a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes to design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The MDA includes an express preemption provision at 21 U.S.C. 360k(a), which states that:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].

See 21 U.S.C. § 360k.

In Riegel, supra, the United States Supreme Court held that the preemption provision of the MDA bars state tort claims insofar as such claims would impose requirements "different from, or in addition to the requirements imposed by federal law," but noted that the provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." See Riegel at 330 (internal citations omitted). To determine whether state law claims are expressly preempted under this framework, the Court established a two-step framework. Id. at 321-22. First, a court must determine "whether the Federal Government has established requirements applicable" to the device at issue. Id. at 321. At the second stage of the analysis, a court must determine whether the claims "are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." Id. at 322. In applying Riegel and interpreting the express preemption

provision of the MDA, the Third Circuit Court of Appeals has noted that the MDA's "comprehensive and tiered approval procedures for medical devices leave only limited room for additional state regulation." See Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 767 (3d Cir. 2018). In order to adequately allege a "parallel" claim that would escape preemption, a plaintiff must generally allege "specific violations of federal law that establish a parallel state duty." See Gross v. Stryker Corp., 858 F. Supp. 2d 466, 491 (W.D. Pa. 2012). "Generalized common law theories of liability" do not suffice to meet this standard. See Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010).

2. Arguments of the Parties

Defendant argues that all of Plaintiffs' claims are preempted by federal law. (Doc. No. 17 at 6.) Specifically, Defendant asserts that the first step of the Riegel analysis concerning whether the federal government has "established requirements applicable to" the device at issue is "irrefutably met because Riegel establishes that [p]remarket [a]pproval of a medical device imposes federal requirements applicable to the device, as a matter of law." (Id. at 6-7) (citing Riegel at 322.) Defendant further argues that, as to the second step of the Riegel analysis, "Plaintiffs' claims are based on Pennsylvania law and challenge the safety and effectiveness of the Proclaim in terms of its FDA-approved and FDA-required design, manufacture, and warnings."[2] (Id. at 8.) Defendant concludes that because Plaintiffs' claims "explicitly relate to

[2] In support of this argument, Defendant requests that the Court take judicial notice of two exhibits: (1) the FDA Premarket Approval letter for the Axium Neurostimulator System (P150004), dated February 26, 2016 (Doc. No. 16-1) and (2) the FDA Premarket Approval letter for the Proclaim Dorsal Root Ganglion Neurostimulation System (P150004/S002), dated November 28, 2016 (Doc. No. 16-2). Federal Rule of Evidence 201(b) permits a district court to take judicial notice of facts that are "generally known within the territorial jurisdiction of the trial court," or facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." See Fed. R. Evid. 201(b). In medical device cases, courts routinely take judicial notice of FDA materials relevant to the device at issue, including materials

the safety and effectiveness of the Proclaim [] and would require the Proclaim to use a different design, different warnings, or a different manufacturing process," those claims seek to impose the type of "different or additional" state law requirements that the Riegel court determined would trigger preemption. (Id.) (citing Gross, 858 F. Supp. 2d at 505).

Defendant also submits that Plaintiffs have not alleged any parallel claims that would allow the amended complaint to survive dismissal. (Id. at 9-11.) Specifically, Defendant notes that Plaintiffs' amended complaint fails to identify any deviation from the FDA's mandated design, manufacturing procedure, and labeling for the device at issue. (Id. at 11.) Defendant further argues that "[c]onclusory allegations and vague references to FDA regulations such as those made here are insufficient to allow claims like Plaintiffs' to survive a motion to dismiss." (Id.) Finally, Defendant argues that even absent preemption, Plaintiffs' amended complaint fails to adequately plead the elements of their claims. (Id. at 13-20.)

Plaintiffs' arguments are limited in scope. Plaintiffs argue generally that their claims avoid preemption because they have "alleged violations of the FDA's current good manufacturing practices as well as alleging that the Proclaim DRG stimulator was subject to recall." (Doc. No. 21 at 3-4.) Plaintiffs insist that "claims based on non-device specific regulations should survive preemption because they fall within the traditional domain of state authority to provide compensation for injured citizens." (Id. at 5.) Further, Plaintiffs assert that their claim for breach of express warranty is not subject to preemption because "a claim for

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related to the device's status as one that was approved through the PMA process. See, e.g., Clements v. Sanofi-Aventis, U.S., Inc., 111 F. Supp. 3d 586, 592 n.2 (D.N.J. 2015) (noting that FDA approvals are matters of public record that are appropriate for judicial notice). Plaintiff has raised no objections to Defendant's request for judicial notice. Accordingly, as the Court concludes that the FDA Premarket Approval letters are appropriate for judicial notice, it will take judicial notice of Defendant's exhibits.

breach of express warranty does not involve a state 'requirement.'" (Id. at 7.) Plaintiffs do not respond to any arguments that their claims are otherwise insufficiently pleaded except to state broadly that "the allegations of the complaint when taken as true do state a valid claim." (Id. at 6.)

3. Whether the Court Should Dismiss Plaintiff's Claims as Preempted

Upon review of the parties' arguments and the applicable law, the Court agrees with Defendant that the majority of Plaintiffs' claims (Counts I, III, IV) are preempted by federal law. As to Count II, Plaintiffs' claim for breach of express warranty, the Court finds that, while it is not subject to preemption, the amended complaint nonetheless fails to state a claim for breach of express warranty and is also subject to dismissal. The Court will consider each count in turn.

i. Negligence (Count I)

Plaintiffs argue that this claim escapes preemption because it is related to the conduct of Defendant's employee and "does not relate to the safety or effectiveness of the device."[3] (Doc. No. 21 at 2.) However, a review of the amended complaint and Plaintiffs' other arguments belies this assertion. Specifically, Plaintiffs' amended complaint alleges that Defendant's negligence involved "failing to provide any repair or other correction to the stimulator" (Doc. No. 11-1 ¶ 23), and Plaintiffs have argued without support that preemption is not implicated because "[t]he safety and effectiveness of [the device] pertains to its ability to provide a patient with pain relief" and that "[t]he FDA approval process does not relate to the device switching

[3] Plaintiffs' have requested that the Court take judicial notice of a series of text messages allegedly from Plaintiff Matthew Conley's cell phone. (Doc. No. 22 at 1.) As noted, supra, note 2, judicial notice is appropriate for facts that are "generally known within the territorial jurisdiction of the trial court," or facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." See Fed. R. Evid. 201(b). The Court does not find that private text messages are a proper subject of judicial notice. Accordingly, the Court declines to take judicial notice of Plaintiffs' Exhibit 1.

into MRI mode" (Doc. No. 21 at 3). Plaintiffs' amended complaint relies on the assertion that there is a defect in the device that prevented it from operating effectively. Further, there is nothing in the FDA letters granting PMA status that would indicate the approval process is limited to only certain aspects of the device's functionality rather than imposing safety and effectiveness standards for the device as a whole. (Doc. Nos. 16-1, 16-2.) Accordingly, the Court finds that Plaintiffs' negligence claim implicates the safety and effectiveness of the device and, therefore, the only remaining inquiry is whether Plaintiffs have alleged a valid parallel claim to survive preemption.

In order to state a claim for negligence under Pennsylvania law, a complaint must allege: (1) a legally recognized duty or obligation of the defendant, (2) the breach of that duty, and (3) a causal connection between the breach and the plaintiff's damages. See Green v. Pa. Hosp., 123 A.3d 310, 315-16 (Pa. 2015). When applied to medical devices that raise federal preemption concerns, the Third Circuit has held that to state a valid parallel claim for negligence, "the 'duty' element must arise from federal requirements applicable to a medical device." See Shuker, 885 F.3d at 776 (citing Riegel, 552 U.S. at 330). The elements of a parallel negligence claim would therefore be: "(1) a duty arising from federal requirements applicable to a medical device, (2) a breach of that duty, and (3) a causal connection between the breach and the [plaintiff's] injuries." See id.

Plaintiffs here have failed to identify any duty arising from the federal requirements applicable to the Proclaim DRG. Instead, Plaintiffs make vague allusions to recalls of the device (Doc. No. 21 at 4) and argue generally that Defendant violated the FDA's good manufacturing practices ("GMPs") (id.). The Court first notes that Plaintiffs have alleged no link between the cited recalls and Plaintiffs' injuries. Further, insofar as Plaintiffs attempt to use the GMPs as the

basis for a parallel claim, courts have regularly found that general citations to the GMPs or federal regulations are not specific enough to sustain a parallel claim.[4] See, e.g., Walls v. Medtronic, Inc., No. 19-cv-3690, 2019 WL 6839942, at *4 (E.D. Pa. Dec. 16, 2019) (dismissing claims as preempted because the plaintiffs failed to identify a specific violation of FDA regulations); White v. Medtronic, Inc., No. 16-cv-2638, 2016 WL 4539494, at *3 (E.D. Pa. Aug. 31, 2016) (finding failure to warn claim preempted where no federal law or regulation required the defendants to warn "users and purchasers of the dangers of the device at issue"); Starks v. Coloplast Corp., No. 13-cv-3872, 2014 WL 617130, at *5 (E.D. Pa. Feb. 18, 2014) (noting that "broad references to federal regulations are insufficient" to state a parallel claim); Gross, 858 F. Supp. 2d at 497 (finding that the GMPs are too vague to establish a parallel claim). Therefore, the Court will dismiss Count I of Plaintiffs' amended complaint as preempted.[5]

[4] Plaintiffs attempt to save their claims from dismissal by arguing that this Circuit "has adopted a line of cases which have allowed cases to avoid preemption based on violations of current good manufacturing practices." (Doc. No. 21 at 4.) Plaintiffs base this assertion on this Court's decision in Silver v. Medtronic, Inc., 236 F. Supp. 3d 889 (M.D. Pa. 2017); however, the Silver decision was premised on the plaintiff's citation to specific violations of identified GMPs acknowledged in warning letters sent by the FDA to the Defendant related to those violations rather than the generalized and conclusory assertions before the Court here. See Silver v. Medtronic, Inc., 236 F. Supp. 3d 889, 897 (M.D. Pa. 2017) (stating that "[t]he [FDA warning] letters provide specific facts to support the FDA's conclusion that [Defendant] was in violation of certain CGMPs").

[5] Furthermore, it is clearly established that Pennsylvania law applies the "learned intermediary doctrine" to failure to warn claims involving prescription drugs and medical devices. See Bull v. St. Jude Med., Inc., No. 17-cv-1141, 2018 WL 3397544, at *7 (E.D. Pa. July 12, 2018) (citing Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010), for the principle that "a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make [a medical device] likely to be dangerous" (emphasis added)). Plaintiffs did not respond to this argument in their brief (Doc. No. 21), but the Court's review of the amended complaint and briefing in this matter makes clear that, even notwithstanding preemption concerns, Plaintiffs' failure to warn claims fail because Defendant's duty to warn does not run to Plaintiffs under Pennsylvania law.

ii. Breach of Express Warranty (Count II)

Plaintiffs assert that their claim for breach of warranty is not subject to preemption because it does not involve a state requirement. (Doc. No. 21 at 7.) The Court agrees with this assertion in the present case. Indeed, various courts within this Circuit have found that express warranty claims escape preemption. See, e.g., Silver v. Medtronic, Inc., 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); White v. Medtronic, Inc., No. 16-cv-2638, 2016 WL 4539494, at *3 (E.D. Pa. Aug. 31, 2016); Bentzley v. Medtronic, Inc., 827 F.Supp.2d 443, 454 (E.D. Pa. 2011). However, the Court will nonetheless dismiss this claim as insufficiently pled under Pennsylvania law.

Under Pennsylvania law, an express warranty is created by: (1) an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain;" (2) a "description of the goods which is made part of the basis of the bargain;" or (3) a "sample or model" that "is part of the basis of the bargain." 13 Pa. C.S.A. § 2313(a). To state a claim for breach of express warranty, a plaintiff must show that the warranty was "directed at consumers in order to induce purchases of the product" and that he "read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." See Gross, 858 F. Supp. 2d at 501 (citing Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004); Sowers v. Johnson & Johnson Med., 867 F. Supp. 306, 314 (E.D. Pa. 1994)). It is well established that "[a]bsent a demonstration that a promise or affirmative statement was made, how or by whom the promise was made, or what was in fact promised," claims for breach of express warranty are not adequately alleged. See id. at 501-502 (citing Delaney v. Stryker Orthopaedics, No. 08-cv-03210, 2009 WL 564243, at *5 (D.N.J. Mar. 5, 2009)). Further, it is clear that where a plaintiff was unaware of any warranty prior to purchase of a product, the warranty could not

have become part of the "basis of the bargain" to give rise to a claim for breach of express warranty. See Parkinson, 315 F. Supp. 2d at 752 (finding that statements made on a defendant's website that the plaintiff became aware of post-sale could not give rise to an express warranty claim).

In the present case, not only have Plaintiffs failed to plead with specificity any details regarding the terms of an express warranty, they appear to acknowledge that they were unaware that any warranty may have existed at all until after Plaintiff Matthew Conley's explant surgery, a year after the device was originally implanted. (Doc. No. 11-1 ¶¶ 16, 19, 27-30.) Specifically, Plaintiffs state only that a telephone conversation took place between Plaintiff Matthew Conley and "an employee and/or representative of the Defendant" on February 27, 2019, during which Defendant's alleged representative "informed the Plaintiff that the Proclaim DRG stimulator had a warranty." Plaintiffs further argue that they "should be permitted to conduct discovery concerning the exact terms of the warranty." (Doc. No. 21 at 7.) The Court finds these limited allegations insufficient to state a claim for breach of express warranty. Accordingly, the Court will dismiss Count II of Plaintiffs' amended complaint.

iii. Failure to Warn (Count III)

Count III of Plaintiffs' amended complaint alleges a claim for negligent failure to warn under the Restatement (Second) of Torts § 388 on the grounds that "Defendant knew or should have known that the DRG was dangerous and had the capacity to cause harm to Plaintiff Matthew Conley" and that Defendant nonetheless "fail[ed] to adequately inform or warn the Plaintiff of the DRG stimulator's dangerous propensity" and "fail[ed] to report the need for corrective action with regard to the use of the DRG stimulator." (Doc. No. 11-1 ¶¶ 32-34.) Insofar as Plaintiffs' claim is that Defendant failed to warn Plaintiff directly, Defendant argued at

length that such a claim is preempted (Doc. No. 17 at 13-16), and it is unclear that Plaintiffs responded to this argument.[6] Plaintiffs instead appear to indicate that this claim is intended as a failure to warn claim premised on an alleged failure to report to the FDA. (Doc. No. 21 at 5-6) (arguing that they have pled a valid parallel claim because "[t]his state duty [to warn third parties of potentially defective conditions] is parallel to FDA reporting requirements because it may impose liability for failure to report to the FDA").

Many courts have found claims based on alleged reporting failures preempted.[7] See, e.g., In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1205–06 (8th Cir. 2010) (noting that claims for failing to report to the FDA are "simply an attempt by private parties to enforce the MDA" and are preempted); Chester v. Bos. Sci. Corp., No. 16-cv-02421, 2017 WL 751424, at *10 (D.N.J. Feb. 27, 2017) (finding failure to warn claim expressly preempted and acknowledging a claim arising from reporting failures would likely be impliedly preempted); Aaron v. Medtronic Inc., 209 F. Supp. 3d 994, 1006 (S.D. Ohio 2016) (dismissing a failure to warn claim premised on alleged reporting failures as expressly preempted). In the cases that allow such claims to move forward, courts have found that a plaintiff must at least "plausibly allege that had [the defendant] properly reported the adverse events to the FDA as required under federal law, that information would have reached [plaintiff's] doctors in time to

[6] Plaintiffs' opposition does not clearly delineate their arguments related to Count I (negligence) and Count III (failure to warn under Section 388). To the extent that Plaintiffs argue generally that Pennsylvania has adopted the Restatement (Second) of Torts § 388 to impose on manufacturers a duty to warn third parties (Doc. No. 21 at 5), as the Court noted, supra note 5, Pennsylvania's duty to warn for medical devices runs to the physician. See Cochran, 3 A.3d at 676.

[7] Failure to report claims have been found both expressly preempted under Riegel and impliedly preempted pursuant to Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), which held that private parties do not have the authority to bring claims because of violations of FDCA requirements. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001).

prevent [plaintiff's] injuries." See Lawrence v. Medtronic, 791 F. App'x 679, 680 (9th Cir. 2020), petition for cert. filed, No. 19-8689 (U.S. June 12, 2020). In addition, a plaintiff must identify "actual adverse events that [a defendant] did not report." See Paturzo v. Bos. Sci. Corp., No. 8:16-cv-2174, 2017 WL 8220600, at *5 (C.D. Cal. Apr. 21, 2017) (internal citation omitted). Plaintiffs here have not even made clear on the face of the amended complaint that this claim is intended as a claim for failure to report to the FDA, and they certainly have not attempted to allege a link between any supposed reporting failures and their injuries. See Shuker v. Smith & Nephew PLC, No. 13-cv-6158, 2015 WL 1475368, at *16 (E.D. Pa. Mar. 31, 2015) (finding no valid parallel claim based on an alleged failure to report to the FDA and dismissing claim with prejudice for failing to allege causation), aff'd, 885 F.3d 760 (3d Cir. 2018). Accordingly, the Court finds that Plaintiffs have failed to state a parallel claim and will dismiss Count III as preempted.

iv. Manufacturing Defect (Count IV)

Count IV of Plaintiffs' amended complaint attempts to state a claim for defective manufacture. In support of this claim, Plaintiffs allege only that: (1) they "believe and therefore aver that [] Defendant manufactured and sold DRG stimulators that were defective" (Doc. No. 11-1 ¶ 36); (2) they "believe and therefore aver that [] Defendant's DRG stimulator was subject to multiple FDA recalls"[8] (id. ¶ 37); and (3) that "Defendant sold [] Plaintiff an adulterated or otherwise non-conforming DRG stimulator as required by the good manufacturing practices of the FDA" (id. ¶ 38). Once again, the Court notes that Plaintiffs have failed to allege any specific

[8] In support of this argument, Plaintiffs request that the Court take judicial notice of FDA recall notices for the device at issue dated March 9, 2008, and September 12, 2017. (Doc. No. 22 at 1.) Defendant does not contest that FDA notices are proper subjects of judicial notice as they are matters of public record. Accordingly, the Court will take judicial notice of the recall notices.

violations of federal law that might establish a parallel state duty. The amended complaint neither identifies a specific manufacturing defect, nor specifically alleges how Defendant's practices ran afoul of FDA requirements. Insofar as Plaintiffs argue this claim can survive preemption due to their reliance on the GMPs, once again, the Court notes that the GMPs are too vague to satisfy the requirements of a parallel claim. See Kubicki v. Medtronic, Inc., 293 F. Supp. 3d 129, 178 (D.D.C. 2018) (holding that "the [GMPs] that Plaintiffs cite are generally insufficient to be the basis for an allegedly parallel state law claim"); Pearsall v. Medtronics, Inc., 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015) (stating that "the [GMPs] are guidelines that do not create a federal requirement" and "[t]o permit a claim that mandates compliance with such 'vague' standards effectively imposes 'different, or additional' requirements, and is preempted"); Gross, 858 F. Supp. 2d at 497 (finding that the GMPs are too vague to establish a parallel claim). Accordingly, the Court will dismiss Count IV as preempted.

B. Leave to Amend

The Third Circuit has "instructed that if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." See Phillips v. Cty. of Allegheny, 515 F.3d 224, 236 (3d Cir. 2008) (citing Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002)). "An amendment is futile if the amended complaint would not survive a motion to dismiss for failure to state a claim upon which relief could be granted." Alvin v. Suzuki, 227 F.3d 107, 121 (3d Cir. 2000) (citing Smith v. NCAA, 139 F.3d 180, 190 (3d Cir. 1998), rev'd on other grounds, 525 U.S. 459 (1999)).

Plaintiffs have requested that they be granted leave to amend their complaint further "to plead more specifically concerning Defendant's failure to notify the FDA about the specific regulation violated." (Doc. No. 21 at 4.) However, the Court does not read Plaintiffs' arguments

to suggest that they have the ability to do so; rather, Plaintiffs have stated that they "should be entitled to discovery to obtain information from Defendant" in order to "more specifically delineate the specific [GMPs] that were violated and exactly how the Defendant was in noncompliance." (Id.) Regarding their breach of warranty claim (Count II), Plaintiffs have also stated that they "should be permitted to conduct discovery concerning the exact terms of the warranty." (Id. at 7.)

Preemption is a matter of law. See Merck Sharp & Dohme v. Albrecht, 139 S. Ct. 1668, 1680 (2019) (holding that preemption based on the nature and scope of FDA actions is an issue of law, not fact). Further, a complaint cannot survive dismissal pursuant to Rule 12(b)(6) because the plaintiff believes that discovery will support otherwise baseless legal conclusions. See Iqbal, 556 U.S. at 678-79 (noting that filing a complaint "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions"). In medical device cases, courts have regularly rejected the argument that plaintiffs are entitled to discovery prior to dismissal on preemption grounds. See Gross, 858 F. Supp. 2d at 503 (collecting cases). As the Court is disinclined to allow Plaintiffs to undertake a discovery fishing expedition, and in light of Plaintiffs' arguments that discovery is necessary to more specifically plead their claims, the Court finds that allowing further amendment in this case would be futile. Accordingly, the Court's dismissal of Plaintiffs' amended complaint is with prejudice.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss (Doc. No. 15) will be granted.[9]

An Order consistent with this Memorandum follows.

[9] Count V of Plaintiffs' amended complaint is a claim for loss of consortium. (Doc. No. 11-1 ¶ 40.) As this claim is derivative of all other claims and Counts I-IV are subject to dismissal, the Court will also dismiss Count V.